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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,525	02/27/2004	Richard James Cawthray	9192ML	7746

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,525

Applicant(s)

CAWTHRAY ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 11, 14, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 11, 14, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments in the Request for Continued Examination, filed January 5, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness – (New Rejections)

1) Claims 1, 2, 4, 11, 14, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Kelly (US 4,817,819).

Daifotis et al. disclose a method of inhibiting bone resorption by administering a bisphosphonate once a week (col. 6, lines 43-50). Administration periods may last from 1 month to about 20 years (col. 7, lines 61-67). The bisphosphonates include alendronate and risedronate. Kits include a card having the dosages oriented in the order of their intended use. An example of such a kit is a blister pack. Blister packs are well known in the packaging industry and are widely used for packaging pharmaceutical

unit dosage forms. If desired, a memory aid can be provided, for example in the form of numbers, letters, or other markings or with a calendar insert, designating the days in the treatment schedule in which the dosages can be administered. Alternatively, placebo dosages, or calcium or dietary supplements, either in a form similar to or distinct from the bisphosphonate dosages, can be included to provide a kit in which a dosage is taken every day (col. 13, lines 48-67). The reference differs from the instant claims insofar as it does not disclose the blister pack comprises a 4 unit dosages of the bisphosphonate and 24 unit dosages of calcium arranged in the order in accordance with Figure 3 or Figure 5.

Kelly discloses a container for tablets. The tablets are stored in a blister pack comprising enough spaces for a twenty-one-day or twenty-four-day cycle (see Abstract). It has been found that utilizing blister packs arranged in seven columns, one for each day, and either three rows or four rows to make up the 21-day or 28-day cycle, provides a satisfactory approach. The blister packs are stored in a container that is labeled with the day that the therapy begins. The reference differs from the instant claims insofar as it does not disclose the tablets are bisphosphonate and calcium.

It would have been obvious to one of ordinary skill in the art to use a blister pack with four rows with seven spaces each to use in the kits of Daifotis et al. motivated by the desire to use a blister pack and container that is labeled with the day therapy begins and is suitable for use for storing pills that are to be taken once a day.

In regards to claims 14 and 26, The Supreme Court has held that while the "teaching, suggestion, motivation" approach is a valid form of analysis under *Graham v.*

Art Unit: 1612

Deere, it is not the only one. See *KSR v. Teleflex*, 82 USPQ2d 1385 (U.S. 2007) at page 1397 where Justice Kennedy, speaking for a unanimous court, states:

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try."... When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

It would have been obvious to one of ordinary skill in the art to have arranged the pharmaceuticals and nutrients as seen in Figure 5 motivated by the desire to arrange the components in a pattern that promotes dosing in a particular order. Since there are only a finite number of ways to arrange the pharmaceuticals and nutrients in the blister packs such as horizontally, vertically and in a circular pattern, it would have been obvious to arrange the components as seen in Figure 5¹.

2) Claims 1, 2, 4, 11, 14, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Allendorff et al. (US 5,265,728).

Daifotis et al. is discussed above and differ from the instant claims insofar as it does not disclose the blister pack comprises a 4 unit dosages of the bisphosphonate and 24 unit dosages of calcium arranged in the order in accordance with Figure 3 and Figure 5.

¹ In any case, a claimed device is not patentably distinct from the prior art if the claimed device would not perform differently than the prior art device. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Allendorf et al. disclose a blister pack comprising enough spaces for a twenty-one-day or twenty-two-day cycle. The blister packs have a symbol for the where to start the disclosed therapy and arrows to ensure that the medication is taken in the right order. The packs may have four rows for 28-day-cycles comprising 7 spaces for each day. The reference differs from the instant claims insofar as it does not disclose the tablets are bisphosphonate and calcium.

It would have been obvious to one of ordinary skill in the art to use a blister pack with four rows with seven spaces each to use in the kits of Daifotis et al. motivated by the desire to use a blister pack and container that is labeled with which pill to start therapy with and has an arrow to direct a patient to the next pill to ensure the medication is taken in the right order.

In regards to claims 14 and 26, The Supreme Court has held that while the "teaching, suggestion, motivation" approach is a valid form of analysis under *Graham v. Deere*, it is not the only one. See *KSR v. Teleflex*, 82 USPQ2d 1385 (U.S. 2007) at page 1397 where Justice Kennedy, speaking for a unanimous court, states:

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try."... When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

It would have been obvious to one of ordinary skill in the art to have arranged the pharmaceuticals and nutrients as seen in Figure 5 motivated by the desire to arrange the components in a pattern that promotes dosing in a particular order. Since there are only a finite number of ways to arrange the pharmaceuticals and nutrients in the blister

Art Unit: 1612

packs such as horizontally, vertically and in a circular pattern, it would have been obvious to arrange the components as seen in Figure 5 (see footnote 1).

Claims 1, 2, 4, 11, 14, 25 and 26 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1612

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612